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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,399	10/07/2003	Saul Kullok	1889.0010001	5808

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EXAMINER

STOICA, MARIA

ART UNIT	PAPER NUMBER
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3715

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/680,399	KULLOK ET AL.	
	Examiner	Art Unit	
	Maria Stoica	3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/7/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 45-46, 54-56, 66, and 86 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Moving a certain item to induce some type of reaction in a subject during any of ascending pressure phase, descending pressure phase, an alpha wave, a beta wave, breathing in, breathing out, systolic phase, and diastolic phase lacks purpose and therefore lacks utility. No motivation is given in any part of the disclosure by the Applicant to account for why this step and part of the apparatus is useful.

2. Claims 73 and 78 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The phrasing "wherein the subject has ..." implies that the Applicant is claiming a human being as part of the invention. This is non-statutory subject matter. Suggested alternate wording: --wherein the apparatus is adapted to serve a subject having ...--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 27-29, 37-40, and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodges et al. (US Patent No. 5,807,114). Hodges discloses a method for treating the condition of a subject comprising the steps of: monitoring a cyclic intrinsically varying physiological activity of the subject (col. 8, lines 64-67); inducing the subject to perform gross motor movements in correlation with the cyclic intrinsically varying physiological activity of the subject (col. 6, lines 14-18); and engaging the subject in operating a hand-operated device to perform a fine motor task (col. 10, lines 61-64).

Regarding claim 28, Hodges discloses that the cyclic internally varying physiological activity of the subject is a cyclic intrinsically varying physiological activity related to cardiac activity or pulse (col. 3, lines 1-4).

Regarding claim 37, Hodges discloses that the method is for treating a subject having a parasympathetic control mechanism and a sympathetic control mechanism and a dynamic balance between the parasympathetic control mechanism and the sympathetic control mechanism (i.e. anxiety, which is controlled by the autonomic nervous system), wherein the method comprises operating the actuator to move the movable surface in correlation with the cyclic intrinsically varying physiological activity of the subject to induce a change in the dynamic balance (col. 10, lines 42-49, lines 64-66).

Regarding claim 40, Hodges discloses that the method is for treating a subject having a parasympathetic control mechanism activity (i.e., anxiousness), wherein the method comprises operating the actuator to move the movable surface in correlation with the cyclic intrinsically varying physiological activity of the subject to improve the parasympathetic control mechanism activity (col. 10, lines 42-49, lines 64-66).

Regarding claim 42, Hodges discloses that the step of operating the actuator to move the movable surface in correlation with the cyclic intrinsically varying physiological activity of the subject further comprises operating the actuator to move the movable surface only during a particular subcycle of the cyclic intrinsically varying physiological activity (col. 11, lines 32-45).

Regarding claims 29, 38, and 43, Hodges discloses that inducing the subject to make gross motor movements in correlation with the cyclic intrinsically varying physiological activity of the subject comprises: placing the subject in contact with a movable surface; and operating an actuator to move the movable surface in correlation with the cyclic intrinsically varying physiological activity of the subject thereby inducing the subject to make gross motor movements in correlation with the cyclic intrinsically varying physiological activity of the subject (col. 10, lines 42-49, lines 64-66).

Regarding claims 39 and 44, Hodges discloses assessing a stress value V from a physiological activity of the subject; and ceasing operating the actuator to move the surface if V passes a threshold T (Figure 5).

4. Claims 47-51 and 57-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodges. Hodges discloses an apparatus for treating a subject wherein the apparatus comprises: a physiological sensor module to monitor a cyclic intrinsically varying physiological activity of the subject (col. 10, line 66 – col. 11, line 5); a moving surface to support the subject (col. 10, lines 42-47); an actuator for moving the moving surface (col. 10, lines 42-47); a hand-operated device for operation by the subject (Figure 1, item 30); and a program module linked to the actuator and the physiological sensor module (Figure 2, items 71-73) wherein the program module causes the mechanical actuator to move the moving surface in correlation with the cyclic intrinsically varying physiological activity of the subject, whereby the subject is prompted to make gross-motor movements in correlation with the cyclic intrinsically varying physiological activity of the subject (col. 10, lines 25-41, lines 64-66).

Regarding claim 48, Hodges discloses that the physiological sensor module comprises a pulse sensor or a cardiac sensor (col. 3, lines 1-4).

Regarding claim 49, Hodges discloses a design for the subject to attempt to follow with the hand-operated device (col. 3, lines 22-25).

Regarding claim 50, Hodges discloses a position monitoring device which monitors the hand-operated device in order to assess a level of performance of the task by the subject (col. 5, lines 23-33, lines 48-52).

Regarding claim 51, Hodges discloses a stress monitor which calculates a stress value V as a function of the cyclic intrinsically varying physiological activity of the subject and terminated the moving of the surface if V passes a threshold T (Figure 5).

Regarding claim 57, Hodges discloses that the method is for treating a subject having a parasympathetic control mechanism and a sympathetic control mechanism and a dynamic balance between the parasympathetic control mechanism and the sympathetic control mechanism (i.e. anxiety, which is controlled by the autonomic nervous system), wherein the method comprises operating the actuator to move the movable surface in correlation with the cyclic intrinsically varying physiological activity of the subject to induce a change in the dynamic balance (col. 10, lines 42-49, lines 64-66).

Regarding claim 61, Hodges discloses that the method is for treating a subject having a parasympathetic control mechanism activity (i.e., anxiousness), wherein the program module operates the actuator to induce an improvement in the parasympathetic control mechanism activity (col. 10, lines 42-49, lines 64-66).

Regarding claim 62, Hodges discloses that the program module causes the mechanical actuator to move the movable surface in correlation with the cyclic intrinsically varying physiological activity of the subject whereby the subject is prompted to make gross-motor movements during a particular subcycle of the cyclic intrinsically varying physiological activity (col. 10, lines 7-40; col. 11, lines 32-45).

Regarding claims 58 and 63, Hodges discloses a stress monitor which calculates a stress value V as a function of the cyclic intrinsically varying physiological activity of the subject and terminated the moving of the surface if V passes a threshold T (Figure 5).

Regarding claims 59 and 64, Hodges discloses a design for the subject to attempt to follow with the hand-operated device (col. 3, lines 22-25).

Regarding claims 60 and 65, Hodges discloses a position monitoring device which monitors the hand operated device in order to assess a level of performance of the task by the subject (col. 5, lines 23-33, lines 48-52).

5. Claims 67-73, 77-80, and 82-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodges. Hodges discloses an apparatus comprising: sensor means for monitoring a cyclic intrinsically varying physiological activity of the subject (col. 10, line 66 – col. 11, line 5); movement means for inducing the subject to make gross-motor movements (col. 10, lines 25-41, lines 64-66); input means for hand operation by the subject (col. 10, lines 61-64); and program module means linked to the movement means for inducing the subject to move in correlation with the cyclic intrinsically varying physiological activity of the subject (col. 10, lines 25-41, lines 64-66).

Regarding claim 68, Hodges discloses that the sensor means is for sensing a cyclic intrinsically varying physiological activity, and comprises a pulse sensor or a cardiac sensor (col. 3, lines 1-4).

Regarding claims 69, 79, and 83, Hodges discloses means for instructing the subject to attempt to move the hand-operated device along a defined path (col. 5, lines 43-56).

Regarding claims 70, 80, and 84, Hodges discloses monitor means for measuring movements of the hand-operated device by the subject (col. 5, lines 50-52).

Regarding claim 71, Hodges discloses means for displaying a design for the subject to attempt to copy with the hand-operated device (col. 12, lines 1-4).

Regarding claim 72, Hodges discloses that the movement means comprises a movable surface in contact with the subject; and actuator means for moving the movable surface in correlation with the cyclic intrinsically varying physiological activity (col. 10, lines 42-49; Figure 5).

Regarding claim 73, Hodges discloses that the subject has a parasympathetic control mechanism and a sympathetic control mechanism and a dynamic balance between the parasympathetic control mechanism and the sympathetic control mechanism (i.e. anxiety, which is controlled by the autonomic nervous system), wherein the program means comprises means for causing the actuator means to move the movable surface in correlation with the cyclic intrinsically varying physiological activity of the subject to induce a change in the dynamic balance (col. 10, lines 42-49, lines 64-66).

Regarding claim 77, Hodges discloses a stress monitor which calculates a stress value V as a function of the cyclic intrinsically varying physiological activity of the subject and terminated the moving of the surface if V passes a threshold T (Figure 5).

Regarding claim 78, Hodges discloses that the subject has a parasympathetic control mechanism activity (i.e., anxiousness), and that the program means comprises means for operating the actuator to move the movable surface in correlation with the cyclic intrinsically varying physiological activity to improve the parasympathetic control system activity (col. 10, lines 42-49, lines 64-66).

Regarding claim 82, Hodges discloses that the actuator means moves the movable surface only during a subcycle of the cyclic intrinsically varying physiological activity (col. 10, lines 7-40; col. 11, lines 32-45; Figure 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 30-32, 41, 46, 52, 55-56, 76, 81, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges in view of Koomar, Greer, and Edmonds.

Regarding claims 30, 41, 46, 52, 55, 76, 81, and 85, although Hodges does not expressly disclose that the method or apparatus for treating the subject comprises treating a learning deficit of the subject selected from the group consisting of Dyspraxia, ADD/ADHD, and Dyslexia, the articles by Koomar, Greer, and Edmonds teach that anxiety is a symptom of all these three disorders. Since Hodges discloses a device to be used to treat anxiety, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method and apparatus disclosed by Hodges to treat patients with Dyspraxia, ADD/ADHD, or Dyslexia in order to assuage anxiety levels of these patients.

Regarding claim 31, Hodges discloses inducing the subject to attempt to copy with the hand-operated device (col. 12, lines 1-4).

Regarding claim 32, Hodges discloses monitoring the subject operating the hand-operated device to perform the task to evaluate the performance of the fine motor task to evaluate the performance of the fine motor task by the subject (col. 5, lines 50-56).

Regarding claim 56, Hodges discloses that the position measuring device comprises a digitizing surface (i.e., the visual display of the virtual reality).

7. Claims 33-36 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges as modified by Koomar/Greer/Edmonds, further in view of Mrklas et al. (US Patent No. 5,304,112).

Regarding claim 33, Hodges, as modified by Koomar/Greer/Edmonds, does not expressly disclose an illuminating means, wherein operating the illuminating means such that a quality of the illumination is changed in correlation to a cyclic intrinsically varying physiological activity of the subject. However, Mrklas teaches this aspect (Abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to alter the method of Hodges, as modified by Koomar/Greer/Edmonds, to allow for a visual indication of the physiological state of the patient.

Regarding claim 34, Hodges discloses a stress monitor which calculates a stress value V as a function of the cyclic intrinsically varying physiological activity of the subject and terminated the moving of the surface if V passes a threshold T (Figure 5).

Regarding claims 35 and 53, Hodges discloses that the design lacks meaning content (for example, being able to stop, accelerate or decelerate an elevator does not make sense in the real world).

Regarding claim 36, the method for treating the subject comprises a method for treating Dyslexia (see claim 30 rejection).

8. Claims 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges in view of Mrklas.

Regarding claim 74, Hodges does not expressly disclose quantitatively assessing a performance level of the subject's attempt to copy the design. However, Mrklas discloses a game to minimize stress and anxiety level, and quantitatively assesses the patient's stress level, comparing it to a target stress level (col. 2, lines 53-57). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the system of Hodges in the way taught by Mrklas to allow for a numerical assessment of how the patient is progressing in the treatment.

Regarding claim 75, Hodges does not expressly disclose an illuminating means, wherein operating the illuminating means such that a quality of the illumination is changed in correlation to a cyclic intrinsically varying physiological activity of the subject. However, Mrklas teaches this aspect (Abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to alter the method of Hodges to allow for a visual indication of the physiological state of the patient.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miranda et al. (US Patent No. 6,457,975) relates to a biofeedback system that uses brain waves to stimulate a subject. Fisslinger (US Patent No. 5,720,619) relates to an interactive biofeedback system. Gevins et al. (US Patent No. 5,724,987) relates to a training system that uses biofeedback. Lamson (US Patent No. 6,425,764) relates to a system for treating psychiatric illnesses through virtual reality with a hand-held controller and patient assessment through quantitative analysis. Blazey et al. (US Patent No. 6,293,904) and Surve et al. (US Patent No. 6,520,905) relate to physiological and psychological state management using images.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Stoica whose telephone number is (571) 272-5564. The examiner can normally be reached on M-F: 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Monica Carter can be reached on (571) 272-4475. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MS


MONICA CARTER
SUPERVISORY PATENT EXAMINER